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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,303	07/06/2001	Geert Maertens	2752-52	3515
23117	7590	07/15/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/899,303

Applicant(s)

MAERTENS ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-70, 73, 74, 76, 79, 85-90, 95, 96 and 102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76, 79 and 85-87 is/are rejected.
- 7) ☒ Claim(s) 68-70, 73-74, 88, 89-90, 95-97 and 102 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION**RCE**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37⁹CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/02/2005 has been entered. The office action on RCE follows:

Response to Amendment

This is a response to the amendment filed on August 30, 2004.

This is a response to the amendment filed on October 27, 2004.

This is a response to the amendment filed On August 30, 2004.

On August 30, 2004, claims 68-70, 73, 7479, 87, 88, 89, 90, 95 96, 97 have been amended. Claim 102 has been added.

On October 27, 2004, claims 95-97 have been further amended.

In summery, the status of claims are summarized as following:

Claims 1-67, 71-72, 75, 77-78, 80-84, 91-94, 98-101 were canceled.

Claims 68-70, 73-74, 76, 85-90, 95-97 and 102 are pending and considered.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Matter Objection

The amendment filed on July 06, 2001 are objected under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added materials which are not supported by the original disclosure are claims 59-61 even though the claims were canceled later.

Amendment filed on December 12, 2001 are objected under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added

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materials, which are not supported by the original disclosure, are claims 77-79, 85 and 86. While claims 77-78 were canceled later, the remaining claims 79, 85 and 86 are still new matters, which are not supported by the specification as it was originally filed.

Because the claimed composition and method of using the vaccine composition comprising a recombinant vector encoding HCV envelope protein have not been disclosed in the application as it was originally filed, Applicant is required to cancel the new matter in the reply to this Office Action.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 79, 85 and 86 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims 77-79 and 85 in the amendment filed on December 12, 2001 introduce a new matter, i.e. a composition comprising a recombinant vector encoding a HCV E1 envelope and a pharmaceutically accepted adjuvant as well as a method of immunizing a mammal comprising administering said composition to said mammal. Application has been carefully reviewed and the application is directed to recombinant vector encoding a HCV envelope protein E1 and method of expressing and purifying the HCV envelope protein E1 as well as a method of using the recombinant HCV envelope protein E1 for diagnosis and immunization. The specification does not teach anywhere to use the recombinant vector encoding a HCV envelope E1 as an immunogenic composition to immunize a mammal. Therefore, the application does not have possession for having such pharmaceutical composition and a method of using the composition to immunize a mammal.

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The case law *Vas-Cath. V. Makurkar*, 19USPQ2d 111, clearly states “applicant must convey with reasonable clarity to those skilled in the art, as of the filing date so long, he or she was in possession of the invention. The invention is, for purpose of the ‘written description’ inquiry, whatever is now claimed.” (see page 1117). The specification should “clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). Moreover, to be in the possession of any claimed invention, the applicants must show that a significance of conception and reduction to practice was reached before the application was filed. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C § 112 is severable from its enablement provision (See page 1115), i.e. even if the claimed method is enabled, it does not mean that applicants has the possession since applicants did not describe or show conception and reduction of practice at the application was originally filed.

In the instant case, while HCV DNV vaccine can be made with recombinant vector according the technique in the art, it only indicates the claimed method may be enabled. However, the claimed invention has not been described sufficiently, In particularity, the application does not describe about how the claimed recombinant vector or vaccinia vector are prepared as an immunogenic composition comprising HCV envelope protein E1 and a pharmaceutical acceptable adjuvant, and how it is used to immunize a mammal. Moreover, applicants have not shown a conception and reduction of practicing the claimed invention at the application was originally filed.

Therefore, the claimed invention in the current application is a new matter and applicants do not have the possession of claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 76, 79 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Grakoui et al. (J. Virol. 1993, Vol. 67, No. 3, pp. 1385-1395).

Grakoui et al. teach a recombinant live vector (pET-3xa/HCV 236-384) that is able to express recombinant HCV envelope protein E1 from amino acid residues 236 to 382 and a composition comprising said vector, wherein the recombinant DNA is expressed under T7 promoter control. Because the E1 peptide only consists of amino acid residue from 236 to 382 it lacks the glycosylation sites present in the position of 196, 209 and 234 of E1 protein inherently at the nucleic acid level (See Table 1 and content on page 1386). Therefore, the claims are anticipated by the cited reference.

Conclusion

Claims 68-70, 73-74, 88-90, 95-97 and 102 are free of rejections. However, they are not in condition for allowance and they may be allowable if applicants cancel the non-allowable claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bao Qun Li MD

07/12/2005